

510(k) SUMMARY

Submitter:	Parkell, Inc. 155 Schmitt Blvd. Box 376 Farmingdale, NY 11735 TEL: 631-249-1134 FAX: 631-249-1242	JUN 15 2006
Contact:	Nelson J. Gendusa, DDS Director of Research Parkell 155 Schmitt Blvd. Box 376 Farmingdale, NY 11735	
Submission Date:	31 March 2006	
Trade Name:	Currently Not Available	
Common Name:	Root Canal Sealer	
Classification Name:	Root Canal Sealing Resin	
Equivalence:	ADSEAL, ENDOREZ, FIRST FILL and SEALAPEX	
Description/Intended Use:	A biocompatible, radiopaque, resin-based, self-etching, dual-cure, two-part (powder/liquid) root canal sealer capable of bonding with gutta percha or resinous points as well as the surrounding walls of a properly reamed and filed root canal to affect a durable seal of that canal.	



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2006

Nelson J. Gendusa, D.D.S.
Director of Research
PARKELL, Incorporated
300 Executive Drive
Edgewood, New York 11717

Re: K060946
Trade/Device Name: CZ-S2000
Regulation Number: 872.3820
Regulation Name: Root Canal Filling Resin Medium large
Regulatory Class: II
Product Code: KIF
Dated: March 31, 2006
Received: April 6, 2006

Dear Dr. Gendusa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

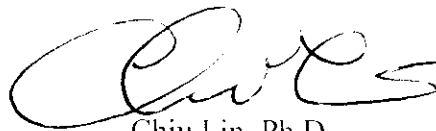
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060946

Device Name: Not yet available.

Indications for Use:

A biocompatible, radiopaque, resin-based, self-etching, dual-cure, two-part (powder and liquid) root canal sealer that is capable of bonding with gutta percha or resinous points as well as the surrounding walls of a properly reamed and filed root canal to affect a durable seal of that canal.

Prescription Use X

AND/OR

Over-The-Counter Use

(21 CFR Part 801 Subpart D)

(21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runne

Special Agent in Charge
Division of Anesthesiology, General Hospital,
Division Control, Dental Devices

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